



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : C11D 3/48, 1/18, A01J 21/00 A01N 35/02, 31/08		A1	(11) International Publication Number: WO 93/10209 (43) International Publication Date: 27 May 1993 (27.05.93)
<p>(21) International Application Number: PCT/US92/10032</p> <p>(22) International Filing Date: 18 November 1992 (18.11.92)</p> <p>(30) Priority data: 07/793,596 18 November 1991 (18.11.91) US</p> <p>(71) Applicant: MEDICAL POLYMERS TECHNOLOGIES, INC. [US/US]; 8920 Business Park Drive, Suite 290, Austin, TX 78759-7405 (US).</p> <p>(72) Inventors: HODAM, Robert, H., Jr. ; 6709 St. Andrews Way, Austin, TX 78746 (US). GOLD, Marvin, H. ; 2601 Latham Drive, Sacramento, CA 95864 (US).</p> <p>(74) Agent: CHWANG, T., Ling, Winstead Sechrest & Minick, 5400 Renaissance Tower, 1201 Elm Street, Dallas, TX 75270-2199 (US).</p>		<p>(81) Designated States: AU, BR, CA, CS, FI, JP, KR, NO, PL, RU, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE).</p> <p>Published <i>With international search report. With amended claims and statement.</i></p>	
<p>(54) Title: POLYMER-BASED CLEANING AND LUBRICATING COMPOSITION</p> <p>(57) Abstract</p> <p>Polymer-based composition effective for disinfecting and for sterilizing plus cleaning and/or lubricating devices. The composition contains, in solution, a hydrophilic polymer serving as a water-based lubricant, a disinfectant, and a surfactant. The addition of a hydrophilic polymer forms an anti-corrosive formula for sterilizing, disinfecting, cleaning, and lubricating devices including medical and dental devices where the efficacy of cleaning and sterilizing is enhanced by the addition of a hydrophilic polymer.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LJ	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TC	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

5

POLYMER-BASED CLEANING AND LUBRICATING COMPOSITION

10

Reference to Related Applications

15 This is a continuation-in-part application of pending U.S. Serial No. 07/793,596, entitled, "Disinfectant Mixture Containing Water Soluble Lubricating and Cleaning Agents and Method", filed 18 November 1991.

Field of the Invention

20 This invention generally relates to a disinfectant mixture containing water-soluble lubricating and cleaning agents. More particularly the present invention relates to a composition for sterilizing, disinfecting, cleaning and lubricating medical and dental devices.

25

Background of the Invention

30 Handpieces are the power units that a dentist utilizes in driving the burs used in the practice of the profession. Most high-speed devices in use today in dentistry are powered by compressed air driving a high speed turbine, which in turn is connected to the various tools and burs used in the patient's mouth. Such turbines may operate at speeds over 400,000 rpm. The bearings in these turbines are usually lubricated with petroleum oils, although there are on the market certain units having ceramic bearings, 35 which are reputed to operate without any lubrication.

40 Nevertheless, when oil is used as a lubricant there are occasions when the oil may be atomized onto or be splashed onto a freshly cleaned or drilled tooth surface, thereby inhibiting good bonding with fillings or plastic coatings used in the reconstruction or preservation of the tooth. Therefore, it would be beneficial to avoid any condition which might allow

oil to enter the mouth during dental procedures. Also, oil stains the device, forming a sticky varnish when heated in an autoclave during sterilization.

Currently, medical devices are typically cleaned daily or weekly by soaking in alcohol, acetone or disinfectant. Typically, there is no cleaning of the device between patients except wiping off the outside. In addition, there is no disinfection or sterilization of devices between patients and there is no lubrication of the devices between patients. In fact, it is impractical to lubricate dental handpieces between patients because typical lubricants used are oil based and have a tendency to cause bonding problems on the teeth due to oil which may come in contact with the enamel on the teeth.

There currently is no practical method to disinfect or sterilize medical devices between patients because chemical baths, chemclaves or autoclaves damage the dental handpieces. In addition, the chemclaves and autoclaves do not remove foreign material such as protein, organisms, and blood from within the dental handpiece. There is therefore a need for a cleaner, which may be a disinfectant and/or sterilant, and lubricant to overcome these difficulties and to make it possible for such devices to be disinfected, lubricated and cleaned between patients.

Summary of the Invention

Generally, the disinfectant mixture of the present invention contains water-soluble lubricating and cleaning agents and is comprised of a hydrophilic polymer. The addition of hydrophilic polymers enhances the performance of both surfactants and sterilants. Exemplary polymers include polyethylene oxides, polyacrylamides, polyvinyl alcohols, polyacrylic acids, polyvinyl pyrrolidones, cellulose derivatives (e.g., methyl cellulose, hydroxethyl cellulose, carboxymethyl cellulose, and the like), polyethylene glycols, and water-soluble silicones or fluoro compounds, which can be used singly or in combination. The mixture also is comprised of a broad range of disinfectants/sterilants which contain anti-microbial chemicals and which are mixable with the hydrophilic polymer to form an aqueous solution for the purpose of disinfection/sterilization and cleaning/lubrication. Disinfectants commonly available which can be used with water-based lubricants include peracetic acids, phenols, alcohols, formaldehyde, glutaraldehyde, quaternary ammonium halides, chlorohexidine, and iodophors. One or more of these disinfectants can be

utilized with a hydrophilic polymer or a combination of hydrophilic polymers to which, if desired, a surfactant can be added.

Specifically, the inventive composition comprises by weight 0.1 to 7.5 percent of a hydrophilic polymer which serves as a water-based lubricant, and 1 to 5 percent by weight of a disinfectant, with the balance being deionized water. Also, 0.1 to 2.5 percent by weight of a surfactant, an anti-oxidant in the range of 0.25 to 1 percent and a dispersant in the range of 1 to 10 percent by weight can be utilized.

10

Detailed Description of the Invention

The present invention involves the addition of hydrophilic polymers with known sterilizing chemicals and surfactants to achieve a potentiation effect which improves anti-microbial efficacy of the sterilants, and cleaning efficacy of the surfactants for the purpose of sterilizing and cleaning out organic debris, such as blood, from medical and dental devices.

The addition of, e.g., polyethylene oxide, to disinfectants also provides a multifunctional product. That is, this invention combines lubricating, disinfecting, sterilizing and cleaning features into one product. The addition of a selected polymer serves to concentrate any water soluble sterilant directly onto microorganisms, thus enhancing the biocidal effect of the sterilant.

25

The polymer of the present invention may also function as a vehicle for concentrating a biocidal chemical on a microorganism. Polymers will adhere to the surface of bacteria, viruses, parasites, plant-like cells, and spores through forces of association and interpenetration of proteins on the cell surface. The selected surfactants enhance this association by allowing close proximity of the polymer to the surface of the organism.

Depending on the microorganism morphology and cell wall biochemistry, the hydrophilic polymers of the present invention have greater or lesser affinity for association. Therefore it is important to include at least one lipophilic surfactant and at least one hydrophilic surfactant to ensure proper wetting of the surface of the organism to maximize the interpenetration and association of the selected polymer. Typically, one might use a combination of sodium laurylsulfate and a polyethoxylated nonylphenol, or sodium dioctyl sulfosuccinate and ammonium

WO 93/10209

polyethoxylated dodecyl phosphate, or octadecyl benzyl dimethyl ammonium chloride and polyethoxylated sorbitan laureate. Once the selected polymer reaches the surface of the organism, a film of polymer forms around the organism. This has two useful functions: to improve cleaning out of 5 organic debris (blood, viable and non-viable organisms, etc.); and, to increase the efficacy of the biocidal active ingredient.

Cleaning is enhanced by incorporating hydrophilic polymers, such as polyethylene oxide or polyacrylamide, because the debris, being covered by 10 a fully hydrated polymer in solution, cannot easily attach to another such piece of debris or to a hard surface such as internal parts of a medical device. Also, cleaning is enhanced because the selected polymer forms a film on internal hard surfaces which prevents blood, organisms and inert debris from attaching or drying onto internal hard surfaces of a medical 15 device.

Sterilization is enhanced by the addition of hydrophilic polymers, such as polyethylene oxide or polyacrylamide, because there are forces of 20 association and hydrogen bonding between water soluble sterilants and the polymers so that chemical biocides tend to concentrate around the polymer. When a selected polymer, carrying the biocide, comes in contact with an organism it attaches as described above, thus concentrating the biocide onto the organism to be killed. For this reason the selection of a specific 25 biocide is not critical to this invention. Any water soluble biocide used with any hydrophilic polymer would behave as described above with varying degrees of increased efficacy.

Generally, the composition of the present invention consists of a water-soluble or water-dispersible disinfecting and/or sterilizing agent, one or 30 more surfactants and a water-soluble polymer having lubricating characteristics. Preferably, the hydrophilic polymer is selected from polyethylene oxides, polyacrylamides, polyvinyl alcohols, polyacrylic acids, polyvinyl pyrrolidones, cellulose derivatives (e.g. methyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose, and the like), polyethylene 35 glycols, and water-soluble silicones or fluoro compounds.

Preferably, the sterilizing disinfecting agent is selected from the group of agents including alcohols, peracetic acid, glutaraldehyde, formaldehyde, phenols, chlorhexidine, polyvinyl pyrrolidone-iodine complexes or other 40 iodophors. One or more of any of the above agents may be used in preparing

the present invention composition. In a preferred form of the invention, glutaraldehyde is used at concentrations in the order of 1 to 5 percent by weight. More particularly, glutaraldehyde is used in concentrations of 2.5 to 4.5 percent by weight.

5

In a preferred form of the invention, polyethylene oxides are used in the molecular weight range of 8,000 to 5,000,000 and/or polyacrylamides in the molecular weight range of 200,000 to 15,000,000. Concentrations of polyethylene oxides in the range of 0.1 to 8.0 percent, depending upon molecular weight, are applicable. Similarly, when polyacrylamides are used, concentrations of about 0.05 to 8.0 percent, preferably about 0.2 to 8.0 percent, are applicable depending on molecular weight.

However, it may not be practical to use systems involving polyacrylamides with aldehydes due to the reactivity of the aldehyde group with amide groups, followed by subsequent intercondensation to form cross-linkages and gelation. In instances where polyacrylamides are the water soluble polymer of choice, one or more of the non-aldehydic sterilants listed above are preferably included.

20

In general, the formulation can be comprised of 0.1 to 8.0 percent of a water-based polymer, 1 to 10 percent of the disinfectant, with the balance being deionized water. If a surfactant is used, it can be added in the range of 0.05 to 2.5 percent by weight of the total formulation preferably in the range 0.1 to 2.0 percent. If desired, an anti-oxidant such as methyl paraben or propyl paraben can be added in the range of 0.05 to 1 percent by weight of the total formulation. A dispersant such as sorbitol, glycerine, propylene glycol, and isopropanol in the range of 1 to 10 percent and preferably 3 to 8 percent by weight is used when polyethylene oxide is incorporated in the mixture.

Polyethylene oxides having molecular weights of 8,000 to 5,000,000 can be used, preferably material in the molecular weight range of 800,000 to 2,000,000 is used to achieve the desired viscosities, adhesions to organisms and lubricity. Using these molecular weights, the range of concentration can be reduced to 0.7 percent to 2 percent. Similarly, preferred molecular weights for the polyacrylamides are in the range of 200,000 to 15,000,000 at concentrations of 0.2 to 10 percent.

Surfactants that may be used in the present composition include salts of long chain alkyl sulfonic acids, salts of alkyl aromatic sulfonic acids, salts of aromatic alkyl sulfonic acids, alkyl polyoxyethyl phosphate esters, aromatic polyoxyethyl phosphate esters, mixed alkyl aromatic polyoxyethyl phosphate esters, alkylated aromatic polyoxyethylethanols, higher alkyl acetylenic glycols and their polyoxyethylethanols derivatives, salts of alkylsulfosuccinates, polyethylene oxide esters of fatty acids, salts of fatty acid amides of amino sulfonic acids, mono- and di-esters of glycerol and polyglycerols, mono- and di-esters of sorbitol, mono- and di-fatty acid esters of sorbitol, polyoxyethyl sorbitan esters, polyoxyethyl sorbitol esters, salts of alkyl polyoxyethyl ethers of propane sulfonic acid, fatty acid amides of diethanol amine, fatty acid amides of morpholine, polyethoxylated fatty alcohols, polyethoxylated fatty amines, alkyl quaternary amine halides, benzyl alkyl quaternary amine halides, and alkyl aromatic quaternary halides.

Although it is possible to have good cleansing and biocidal activity with the use of only one surfactant, it may be advantageous to use two or more different surfactants in order to thoroughly wet and coat all hard surfaces and swell any biofilm or deposited material on or within the medical device and therefore effectuate its removal. Using mixed surfactants may allow thorough wetting and swelling of the outer coat of any organism or virus, so that the sterilant can more readily penetrate and destroy that organism. For example, one may use a combination of a quaternary ammonium halide with a polyethoxylated nonyl phenol, a combination of alkylbenzene sulfonate salt with an aromatic polyethoxylated phosphate ester salt. Both of these combinations may be combined with an additional long chain acetylenic glycol or polyethoxylated acetylenic glycol. Some of these combinations have the additional feature of being not only powerful detergent solutions but also contributing toward corrosion inhibition.

When glutaraldehyde is used as the biocidal agent, the biocidal activity is most rapid in alkaline solution. However, it may not be practical to operate at the higher pH levels with this reagent. Glutaraldehyde may undergo self-condensation by means of the Aldol Condensation and this rate is enhanced in an alkaline medium. Therefore, it may be preferable to keep the reaction mixtures at pH levels of 5 or lower, in order to maintain good shelf life. Preferably the pH is between about 3 to about 5 for storage. The pH may be raised to between 7 to 8 at the time of use, using sodium

bicarbonate or triethanolamine as a buffer. Also, polyacrylamide may not be suitable as a polymer with glutaraldehyde for the same reasons.

Polyethylene oxide polymer chains typically are affected by oxidative degradation at the ether linkages. For this reason, an anti-oxidant may be added to solutions containing this polymer to preserve the molecular weight. Water-soluble or water-dispersible esters of parahydroxybenzoic acid, i.e., methyl or propyl paraben, are preferably used with polyethylene oxide. There are many other anti-oxidants which may be used, such as a variety of phenolic compounds, ascorbic acid, polyunsaturated compounds, and aromatic amines. Generally, combinations of aromatic amines and aldehydes should be avoided.

Another problem associated with the use of polyethylene oxides, is that they are produced as fine fluffy powders. Thus, when they are to be dissolved in water, there is a tendency for the particles to agglomerate and form intractable gels. Union Carbide, a major manufacturer of these products, has provided designs for equipment to be used in large scale operations with these polymers. However, for small scale laboratory work it is frequently more feasible to suspend the polymer powder in a non-solvent liquid, miscible with water and drip this slurry into a well- stirred water solution. For this reason, it may be practical to work with slurries of the polymer in solvents such as glycerol, propylene glycol, isopropanol, ethanol, and the like.

On the other hand, the polyacrylonitriles are produced in coarse, granular form and do not have the mechanical problems of solution experienced with the polyethylene oxides, therefore, they do not require use of the suspending solvents. Also, the polyacrylonitriles are not subject to chain degradation by oxidative cleavage and do not require anti-oxidants for preservation. In view of the above stated conditions, the following examples are provided as illustrative of, but not limiting to, the claimed composition.

35 Exemplification

Example 1

One specific formulation found to be particularly satisfactory is comprised of the following constituents in percentages by weight:

0.7% Polyethylene Oxide, 1,000,000 MW
5.0% Denatured Ethanol
4.0% Glutaraldehyde
Balance Deionized water

5

When a surfactant is used in this specific formulation, it is introduced into the formulation in the following percentages by weight:

0.5% Quaternary ammonium chloride
or
10 0.5% Nonoxytol-9

Alternatively, a mixture of the two can be used at the same percentage. When an anti-oxidant is utilized, it is introduced into the formulation in the following percentages by weight:

15 0.2% Methyl paraben or propyl paraben

Example 2

Another formulation found to be particularly desirable had the following constituents in percentage by weight:

5	0.7%	Polyethylene oxide, 2,000,000 MW
	4.0%	Glutaraldehyde
	0.1%	Quaternary ammonium chloride
	0.7%	Noxynol-9
	0.2%	Methyl paraben
10	0.2%	Propyl paraben
	8.0%	Glycerine
	Balance	Deionized water

Example 3

15	Another formulation is:	
	0.5%	Polyacrylamide, 5,000,000 MW
	0.7%	Quaternary ammonium chloride
	0.5%	Noxynol-9
20	Balance	Deionized water

Example 4

To 21 g of polyethylene oxide having a molecular weight of about 25 1,000,000 add 3.75 g of methyl parahydroxybenzoate (methyl paraben) and 1.95 g of propyl parahydroxybenzoate (propyl paraben). These are ground together with a mortar and pestle and then suspended in 135 g propylene glycol and 30 g isopropanol to make a thick slurry. This slurry is then slowly poured into 2500 ml of deionized water. Stirring is continued for at 30 least one hour to effectuate complete solution of the polymer and then 6 g polyethoxylated acetylenic glycol (such as Surfynol 440TM, available from Air Products Co.), 3 g of an aromatic polyethoxylated phosphate ester (such as Maphos 91TM available from Mazer Division of PPG), and 3 g of an alkylaromatic sulfonic acid (such as Biosoft-100TM available from Stepan 35 Chemical) are added and mixed for five minutes, then 400 g of 50% glutaraldehyde is added. The pH of this solution is about 3. Titration with 10% sodium bicarbonate may be used to bring the pH up to 7.

Example 5

To 7 g of polyethylene oxide having a molecular weight of 2,000,000 is added 1.25 g of methyl paraben and 0.65 g of propyl paraben. These are ground together with a mortar and pestle and suspended in 45 g of propylene glycol and 15 g isopropanol to make a thick slurry. Then, 2 g of a 5% solution of dodecyl benzyl dimethyl ammonium chloride, such as BTC-50™, available from Stepan Chemical, is added, followed by 4 g nonoxynol-50™, available from Stepan Chemical, is added, followed by 4 g nonoxynol-9 and 40 g 50% glutaraldehyde. This mixture is added to 925 ml of water. The pH of this solution is about 3 and it may be raised to pH 7 by titration with 10% sodium bicarbonate. In this example, propylene glycol reduces evaporation of the mixture in high speed devices, thus improving lubrication.

Example 6

To 21 g of 2,000,000 molecular weight polyethylene oxide is added 5.8 g methyl paraben. The two are ground together with a mortar and pestle and slurried in 60 g isopropanol. The slurry is slowly poured into 2745 ml deionized water and the container is rinsed with an additional 30 ml isopropanol and poured into the stirred solution. Stirring is continued at least one hour to effect complete solution and 6.5 g of a 50% solution of dodecyl benzyl dimethyl ammonium chloride, such as BTC-50, 10 g Nonoxynol-9™ and 180 g 50% glutaraldehyde are added. Titration with 10% sodium bicarbonate raises the pH from 3 to 7.

Example 7

A solution of 0.1% polyacrylamide (15,000,000 molecular weight) was prepared by slowly adding 1 g of the polymer to 850 ml well-stirred deionized water. Solution should be complete after stirring two hours. Then, 136 g of polyvinyl pyrrolidone-iodine complex (11% iodine) is slowly added to the well-stirred solution. This is followed by the addition of 1.5 grams dodecylbenzene sulfonic acid and 2 g of polyethoxylated sorbitan oleate. The solution is finally titrated with 50% triethanolamine to a pH of 6.5.

Example 8

A solution of 0.6% polyacrylamide (5,000,000 molecular weight) is prepared by slowly adding 6 g of polymer to 850 ml deionized water.

5 Solution should be complete after stirring 2 hours. Then, 136 g of polyvinyl pyrrolidone-iodine complex (11% iodine) is carefully stirred in, followed by the addition of 1.5 g of a linear alkane sulfonate and 2 g of an alkyl polyethoxylated sulfonic ester. Titration with 10% sodium hydroxide should bring the pH up to 6.5.

10

Example 9

To 7 g of 2,000,000 molecular weight polyethylene-oxide is added 1.8 g methyl paraben and the two are ground together with a mortar and pestle.

15 This mixture is then slurried with 45 g of propylene glycol, slowly poured in a thin stream into 900 ml deionized water. Upon complete solution, 1.5 g of dodecylbenzene sulfonic acid, 2 g of an ethoxylated nonylphenol phosphate ester, 0.6 g of an ethoxylated alkyl acetylenic glycol and 40 g of 50% glutaraldehyde are washed in with isopropanol. The resulting solution 20 is titrated with 10% sodium bicarbonate to raise the pH from 3 to 7.

This latter Example 9, without glutaraldehyde, has the synergistic effect of providing the desired lubricity and cleaning, with a high degree of corrosion resistance for the various types of metals used in making up

25 most modern medical devices. Although the body of most devices may be made of stainless steel, some are still made of ordinary steels and the units may also have internal components of aluminum, brass, zinc or copper. In addition, there are gaskets and seals, made of a variety of rubbers and plastics. The present composition avoids the swelling and 30 destruction of these rubbers and plastics. The addition of glutaraldehyde creates a solution that lubricates, cleans, protects against corrosion, and disinfects and/or sterilizes.

Example 10

35

Mix 1.8 g of methyl paraben and 7 g of 2,000,000 molecular weight polyethylene oxide and grind to a fine powder. Mix the powder into 45 g propylene glycol. When dispersed, mix slurry slowly into 900 ml deionized water. When solution is completely clear add 1.5 g of dodecylbenzene 40 sulfonic acid, 2 g of ethoxylated nonylphenol phosphate ester, and 0.6 g of

ethoxylated alkyl acetylenic glycol washed in with 10 ml of isopropanol. The resulting solution is buffered to pH 6.5 with triethanolamine. This formula makes a cleaner/lubricant composition. The molecular weight of the polyethylene oxide can be lowered to 8,000 without appreciable change in lubricity for medical devices that require a lower viscosity.

Formulations using polyacrylamide typically do not require dispersants or anti-oxidants. Dispersants may not be required due to the high solubility of polyacrylamide in water. Anti-oxidants may not be required since polyacrylamide is very stable; however, they may be added to enhance the corrosion resistance of the formulation.

Regarding Examples 1, 2, 4-6 and 9, the active ingredient for disinfection and/or sterilization is glutaraldehyde. The surfactants, quaternary ammonium chloride and nonoxynol-9, both operate synergistically with glutaraldehyde to provide surface wetting. The two surfactants have different chemical structures and therefore provide different wetting characteristics for different kinds of proteins, and thus tend to provide a broad range of high level surface wetting which should reach most proteins. These surfactants not only make the surfaces of the proteins wet, but also swell the cells so as to receive glutaraldehyde and to make the glutaraldehyde more effective in a shorter period of time. It is believed that the surfactants provide openings in the protein in the organism, allowing the glutaraldehyde to penetrate that organism. These surfactants also act as lubricants to aid in lubrication. However, since they are surfactants, their primary purpose is to emulsify proteins, blood, other foreign matter and saliva which become attached to the internal parts of dental handpieces.

Examples 7 and 9 describe a composition that functions as a disinfectant, cleaner, and lubricant. Examples 3 and 10 describe a composition that functions as a cleaner and lubricant only. Each Example functions as a lubricant.

The disinfectant/sterilant composition can be prepared by mixing the various liquid ingredients in a vat at room temperature and stirring the same. The mixture can then be packaged in suitable containers, as for example plastic or glass bottles, and shipped in cartons for use by the dentist.

Use of the disinfectant/sterilant composition by the dentist in a method in accordance with the present invention for treating dental handpieces may now be briefly described as follows. Although the following description is directed to the use of the inventive composition in a dental

5 device environment, the method and composition apply equally to the medical device environment and any other environment at which such a disinfecting, sterilizing, cleaning, and lubricating composition would be desirable.

10 In practicing the present invention, the doctor, dentist or staff member would pour a bottle of the inventive sterilizing, cleansing, disinfecting, lubricating composition into a suitable sized glass or plastic tray or other container, to such a depth that it completely cover the device lying in that container. The device would be allowed to remain immersed in the solution
15 for at least ten hours at room temperature to achieve sterilization or at least 30 minutes if heated to 40°C in order to achieve sterilization, and shorter periods, in the range of several minutes, if only disinfection is required. This allows the liquid to penetrate into the device. The device may be extracted from the solution and be allowed to drain on any
20 absorbent material, such as a paper towel, for a few seconds. Any remaining free liquid may then be removed by any of a variety of means, such as wiping with a paper towel or cotton swab. In the case of a dental-handpiece it may then be reconnected to its compressed air line and excess internal liquid blown out. It would then be ready for use or if desired it
25 could be rinsed in clean water to remove dead organisms, autoclaved then immersed in the solution after autoclaving to reestablish a chemical film on the device.

Alternatively, disinfectant/cleaner lubricating solutions may be
30 injected into the dental-handpiece by means of any of a variety of hydraulic devices, liquid guns, or air pressure from the same source as is used to operate the device. As the liquid moves through the head of the device it disinfects, cleans and lubricates the device. At the same time it flushes any accumulated blood, saliva and other deposits, out through the
35 opening in the head of the device. Again, after at least one minute the dental-handpiece may be disconnected from the gun and be readied for use on the next patient.

Similarly, if a compressed air gun were not available, it may be possible
40 to inject the disinfecting lubricant into the device by means of a syringe

specifically designed for the purpose, or to immerse the device in the solution in heated or unheated ultrasonic device to aid cleaning.

5 In another format practicing the present invention, the dentist or the dental assistant can take a container or bottle of a disinfectant or a sterilant composition of the present invention and pour the liquid mixture into a tray formed of a suitable material such as autoclavable glass or stainless steel. The tray can be of any suitable size and shape and can be rectangular in form having an open top side. It can be of a suitable size 10 such as 4 inches in width, 8 inches in length, and approximately 3 inches in depth. The tray can be provided with a cover which can be utilized for covering the top side opening.

15 The dental handpiece to be disinfected in accordance with the present invention is disconnected from its compressed air line, placed in the liquid in the tray, and allowed to remain therein at room temperature for a period of at least 10 minutes, permitting the liquid to penetrate into the water and air lines and into the head of the dental handpiece. The dental handpiece may then be extracted from the liquid by suitable means such as 20 by the use of tongs. It should be appreciated that although the human hand can be inserted into the liquid to retrieve the handpiece, this is undesirable because of the need to maintain the cleanliness or purity of the liquid in the tray.

25 After the dental handpiece has been retrieved from the liquid, it is permitted to drain onto a paper towel for a period of a few seconds. Any remaining liquid on the handpiece can then be removed by a suitable manner, such as paper towel or by cotton swabs. The dental handpiece is then reconnected to its compressed air lines. The air line is then turned 30 on, blowing out the excess liquid from the air lines and the water lines and in the other parts of the dental handpiece, after which the dental handpiece can be placed in service for use with the next patient.

35 For lubricating purposes, the dental handpieces could be permitted to soak in the liquid disinfectant by first forcing the liquid through the dental handpiece until it appears at the head. The dental handpiece could then be permitted to soak for a period of 2 to 5 minutes, after which the gun or the syringe used to introduce the composition into the device can be utilized to force additional disinfectant into the dental handpiece to further clean, 40 disinfect and lubricate the dental handpiece.

When a tray is used for containing the liquid, it is believed that disinfectant/sterilant will be effective for at least one week and up to one month. For example, on each Monday morning, at the first of the week, the 5 dentist or the dental assistant can take a clean tray, fill it with the inventive disinfectant/sterilant, and cover it until use. The disinfectant may be supplied so that it need not be diluted prior to use. It can be poured into the tray to the desired level and used for the entire week. At the end of the week, as for example on Friday, after the dentist has ceased work 10 for the week, the disinfectant contained in the tray can be disposed of and the tray cleaned and dried for use on the following Monday.

The present invention is particularly efficacious for disinfecting and/or sterilizing dental handpieces to prevent the transmission of disease from 15 one patient to the other. The disinfectant mixture also has other advantages in that it cleans out blood and saliva from inside and outside dental handpieces when used between patients. Oil-free lubrication is provided which eliminates bonding problems encountered with previous lubricants. The disinfectant mixture is also non-corrosive. Its use is 20 advantageous because it provides extended handpiece life. It also makes possible lower operating costs for the dentist. The need for expensive oil lubricants is eliminated, which is particularly desirable because the removal of oil lubricants from dental handpieces in the past has required the use of strong solvents to clean out carbon build-up and organic matter. 25 The water-based lubricants utilized in the disinfectant mixture of the present invention are water-soluble and can be washed out with warm water.

A sporicide test was performed on the formulation of Example 10, using 30 the prescribed protocol of the American Organization of Analytical Chemists (AOAC). The AOAC test is used to determine sporicidal activity on EPA porcelain cylinder carriers (Clostridium sporogenes). The spores used were C. sporogenes with HCl preservative. The frozen spore suspension was diluted up to 10^5 spores per milliliter sterile deionized water. The spore samples were aliquoted 9.0 ml into 20 mm porcelain 35 cylinders. The cylinders were then placed into a water bath at a temperature of 45°C, for 30 minutes before initiation of the test. A control experiment was performed by aliquoting 9.0 ml sterile deionized water into a 20 ml glass test tube and was placed into 45°C water bath.

1.0 ml of the diluted C. sporogenes spore suspension was added to 9.0 ml of each sample and mixed. These were then placed back into a 45°C water bath. At each time interval, the sample was mixed and a 1.0 ml sample was taken out into 9.0 ml Fluid Thioglycollate Medium (FTM) broth containing 7.5% glycine (10⁻¹ dilution). A further ten-fold serial dilution was made into 9 ml broth containing 2% glycine. The data in the following Table I demonstrate the effect of exemplary contact times for the composition of Example 10 at the stated pH values.

10

TABLE I

AOAC SPORICIDE TEST FOR STERILIZATION

15

NUMBER OF CYLINDERS POSITIVES/NUMBER TREATED WITH
GERMACIDE SOLUTIONS

	Contact Time (Minutes)	pH 7	pH 7.5	pH 8.0	pH 8.5
20	15	6/30	4/30	4/30	6/30
	30	0/30	3/30	6/30	1/30
	60	0/30	1/30	2/30	2/30

Chemosterilization is achieved for those samples having ratios of 0/30, whereas disinfection is shown for samples exhibiting ratios of 1/30 or less. Thus, chemosterilization at 45°C is feasible at less than one hour for compositions at pH 7.0. High level disinfection at 45°C in less than 15 minutes appears feasible.

What is claimed is:

1. A composition having lubricating and cleaning properties, comprising, in solution, a surfactant, and a hydrophilic polymer selected from the group consisting of: polyethylene oxides; polyacrylamides; polyvinyl pyrrolidones; cellulose derivatives; polyvinyl alcohol; polyacrylic acids, and, water-soluble silicones and fluoro compounds.
- 5 2. The composition of claim 1 wherein the polyacrylamides are selected from the group of polyacrylamides having a molecular weight in the range of about 200,000 to about 15,000,000.
- 10 3. The composition of claim 2, wherein the polyacrylamide constitutes, by weight, about 0.2 percent to about 10 percent.
- 15 4. The composition of claim 1 wherein the surfactant is selected from the group consisting of: dodecylbenzene sulfonic acid; ethoxylated nonylphenol phosphate ester; and ethoxylated alkyl acetylanic glycol.
- 20 5. The composition of claim 4 wherein the surfactant constitutes, by weight, about 0.05 percent to about 2.0 percent.
- 25 6. The composition of claim 1, wherein the polyethylene oxides are selected from the group of polyethylene oxides having a molecular weight in the range of about 800,000 to about 2,000,000.
7. The composition of claim 6, wherein the polyethylene oxide constitutes, by weight, about 0.1 percent to about 2 percent.
- 30 8. The composition of claim 1 further comprising a lipophilic surfactant and a hydrophilic surfactant.
9. The composition of claim 8 further comprising pairs of said lipophilic surfactant and said hydrophilic surfactant selected from the group consisting of: sodium lauryl sulfate and polyethoxylated nonyl phenol; sodium dioctyl sulfosuccinate and ammonium polyethoxylated dodecyl phosphate; and, octadecyl benzyl dimethyl ammonium chloride and polyoxylated sorbitan laurate.
- 35 10. The composition of claim 1 further comprising an anti-oxidant.

11. The composition of claim 10 wherein the anti-oxidant is selected from the group consisting of water-dispersible esters of parahydroxybenzoic acid, phenols, ascorbic acid, and aromatic amines.
- 5 12. The composition of claim 1 wherein the composition is at a pH of between about 3 and about 5.
13. The composition of claim 1 wherein the composition is at a pH of between about 7 and about 8.
- 10 14. The composition of claim 1 further comprising a disinfectant.
15. The composition of claim 14 wherein the disinfectant is selected from the group consisting of: peracetic acid, phenols; alcohols; formaldehyde; glutaraldehyde; chlorohexidine; iodophors; and polyvinyl pyrrolidone-iodine complexes.
- 20 16. The composition of claim 14 wherein, by weight, the hydrophilic polymer constitutes from about 1.0 percent to about 8.0 percent, the disinfectant constitutes from about 1 percent to about 10 percent, and the surfactant constitutes from about 0.1 percent to about 2.0 percent.
- 25 17. The composition of claim 16 wherein the polyethylene oxides are selected from the group of polyethylene oxides having a molecular weight in the range of about 800,000 to about 2,000,000.
- 30 18. The composition of claim 14 further comprising, by weight, about 0.1 percent to about 2 percent polyethylene oxide, about 0.1 percent to about 2 percent surfactant, and about 1 percent to about 10 percent disinfectant.
- 35 19. A composition having lubricating and disinfecting properties, comprising, in solution, a disinfectant and a hydrophilic polymer selected from the group consisting of: polyethylene oxides; polyacrylamides; polyvinyl pyrrolidones; cellulose derivatives; polyvinyl alcohol; polyacrylic acids, and, water-soluble silicones and fluoro compounds.
- 40 20. The composition of claim 19 wherein the disinfectant is selected from the group consisting of: peracetic acid, phenols; alcohols; formaldehyde; glutaraldehyde; chlorohexidine; iodophors; and polyvinyl pyrrolidone-iodine complexes.

AMENDED CLAIMS

[received by the International Bureau on 18 April 1993 (18.04.93); original claims 1,9,19 and 20 amended; remaining claims unchanged (3 pages)]

1. A composition having lubricating and cleaning properties, comprising, in solution, a surfactant, water, and a hydrophilic polymer selected from the group consisting of: polyethylene oxides; polyacrylamides; polyvinyl pyrrolidones; cellulose derivatives; polyvinyl alcohol; polyacrylic acids; and water-soluable silicones and fluoro compounds.

2. The composition of claim 1 wherein the polyacrylamides are selected from the group of polyacrylamides having a molecular weight in the range of about 200,000 to about 15,000,000.

3. The composition of claim 2, wherein the polyacrylamide constitutes, by weight, about 0.2 percent to about 10 percent.

4. The composition of claim 1 wherein the surfactant is selected from the group consisting of: dodecylbenzene sulfonic acid; ethoxylated nonylphenol phosphate ester; and ethoxylated alkyl acetylanic glycol.

5. The composition of claim 4 wherein the surfactant constitutes, by weight, about 0.05 percent to about 2.0 percent.

6. The composition of claim 1, wherein the polyethylene oxides are selected from the group of polyethylene oxides having a molecular weight in the range of about 800,000 to about 2,000,000.

7. The composition of claim 6, wherein the polyethylene oxide constitutes, by weight, about 0.1 percent to about 2 percent.

8. The composition of claim 1 further comprising a lipophilic surfactant and a hydrophilic surfactant.

9. The composition of claim 8 further comprising pairs of said lipophilic surfactant and said hydrophilic surfactant

selected from the group consisting of: sodium lauryl sulfate and polyethoxylated nonyl phenol; sodium dioctyl sulfosuccinate and ammonium polyethoxylated dodecyl phosphate; and octadecyl benzyl dimethyl ammonium chloride and polyoxylated sorbitan laurate.

10. The composition of claim 1 further comprising an anti-oxidant.

11. The composition of claim 10 wherein the anti-oxidant is selected from the group consisting of water-dispersible esters of parahydroxybenzoic acid, phenols, ascorbic acid, and aromatic amines.

12. The composition of claim 1 wherein the composition is at a pH of between about 3 and about 5.

13. The composition of claim 1 wherein the composition is at a pH of between about 7 and about 8.

14. The composition of claim 1 further comprising a disinfectant.

15. The composition of claim 14 wherein the disinfectant is selected from the group consisting of: peracetic acid; phenols; alcohols; formaldehyde; glutaraldehyde; chlorohexidine; iodophors; and polyvinyl pyrrolidone-iodine complexes.

16. The composition of claim 14 wherein, by weight, the hydrophilic polymer constitutes from about 1.0 percent to about 8.0 percent, the disinfectant constitutes from about 1 percent to about 10 percent, and the surfactant constitutes from about 0.1 percent to about 2.0 percent.

17. The composition of claim 16 wherein the polyethylene oxides are selected from the group of polyethylene oxides having a molecular weight in the range of about 800,000 to about 2,000,000.

18. The composition of claim 14 further comprising, by weight, about 0.1 percent to about 2 percent polyethylene oxide, about 0.1 percent to about 2 percent surfactant, and about 1 percent to about 10 percent disinfectant.

19. A composition having lubricating and disinfecting properties, comprising, in solution, a disinfectant, water, and a hydrophilic polymer selected from the group consisting of: polyethylene oxides; polyacrylamides; polyvinyl pyrrolidones; cellulose derivatives; polyvinyl alcohol; polyacrylic acids; and water-soluble silicones and fluoro compounds.

20. The composition of claim 19 wherein the disinfectant is selected from the group consisting of: peracetic acid; phenols; alcohols; formaldehyde; glutaraldehyde; chlorohexidine; iodophors; and polyvinyl pyrrolidone-iodine complexes.

STATEMENT UNDER ARTICLE 19

The claimed invention of the present application is a polymer-based disinfectant/lubricant. The claimed composition is an anti-corrosive formula for sterilizing, disinfecting, cleaning, and lubricating devices, including medical and dental devices.

A. U.S. Patent No. 4,389,320 (Clampitt) discloses a thermally stable gelled composition suitable for post-primary oil and gas well recovery comprising: water, a surfactant, a polymeric viscosifier, an aldehyde component, and at least one phenolic component. Clampitt's invention solves a non-analogous problem to that of the present invention and is in a non-analogous art.

Clampitt teaches the inclusion of a water-thickening, water-dispersible polymer. The claimed invention recites a solution, not a gel, containing a hydrophilic polymer. The only apparent purpose of Clampitt's inclusion of a polymer is to gel the composition in the presence of the required aldehyde and phenol. On the other hand, the purpose of the hydrophilic polymer in the present invention is to serve as a

lubricant to reduce friction between moving parts. Clampitt, by requiring the gelation of the disclosed invention teaches away from the claimed invention, since a gel would not effectively penetrate the spaces between moving parts.

Accordingly, Applicant respectfully submits that the present invention would not have been obvious in view of Clampitt as the type of ingredients and their concentrations were selected for totally different criteria and requirements, i.e., the formation of a gel versus a liquid.

B. U.S. Patent No. 4,753,844 to Jones et al. discloses semi-moist wipes for cleaning windows and other hard surfaces. These wipes contain an aqueous composition which contains: water, water miscible solvents for oils and dirt, and sufficient ammonia or alkaline metal hydroxide to maintain a pH between 8.0 to 12.0.

The composition as disclosed by Jones et al. requires a water miscible solvent as its major component. Preferred solvents are the lower aliphatic water miscible alcohols or glycols present from 9% to 70% wt/wt. (col. 7, lines 6-35).

In contrast, the claimed invention does not require the inclusion of a water miscible solvent for oils and dirt. Although alcohols are given as an example of an effective disinfectant in the claimed mixture, the claimed concentration is much less than that disclosed by Jones et al. for their water miscible solvent. Furthermore, the present invention requires that any alcoholic disinfectant be used in conjunction with a water based lubricant.

Applicant submits that the claimed invention would not have been obvious in light of Jones et al. Jones et al. teach a composition for cleaning surfaces, not for leaving a film of lubricant.

Neither Clampitt nor Jones et al. solve the same type of problem as the present invention. Thus, Applicant submits that the present invention would not have been obvious to the average person skilled in the art in light of either or both of these patents.

INTERNATIONAL SEARCH REPORT

PCT/US92/10032

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :C11D 3/48, 1/18; A01J 21/00; A01N 35/02, 31/08

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 252/106, 174.21, 174.23, DIG. 2, 547, 174.15; 424/405; 514/694, 705, 693, 731, 724

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,173,653 (Law) 06 November 1979, See columns 3-5.	1-20
A	US, A, 4,632,772 (Gavabedian et al.) 30 December 1986, See column 5, lines 24-53, and Table I.	1-20
Y	US, A, 4,389,320 (Clampitt) 21 June 1983, See claim 1.	1-20
Y	US, A, 4,753,844 (Jones et al.) 28 June 1988, See columns 7-10.	1-20

 Further documents are listed in the continuation of Box C. See patent family annex.

• Special categories of cited documents:		
A document defining the general state of the art which is not considered to be part of particular relevance	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
E earlier document published on or after the international filing date	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
O document referring to an oral disclosure, use, exhibition or other means	*&*	document member of the same patent family
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

13 JANUARY 1993

Date of mailing of the international search report

02 MAR 1993

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized official

NHAT PHAN

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-3795

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/10032

A. CLASSIFICATION OF SUBJECT MATTER:
US CL :

252/106, 174.21, 174.23, DIG. 2, 547, 174.15; 424/405; 514/694, 705, 693, 731, 724